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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,359

07/15/2004

Domenico Fanara

2004\_1045A

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7590

08/05/2009

WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,359	<b>Applicant(s)</b> FANARA ET AL.	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 May 2009 &amp; 13 May 2009</u> .                           | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed May 27, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claim 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510) and Reiner et al. (US 5,711,961).

#### **Applicant's Arguments**

Applicant asserts unexpected results and submits a declaration filed under 37 CFR 1.132. The large reduction of degradation seen in the bilayer tablet is highly unexpected.

#### **Examiner's Response**

Based on the declaration and what is asserted to be known in the art by Declarant, it does not appear that the results are unexpected. One of ordinary skill in the art would reasonably conclude that less degradation would occur because the two components are not mixed together and therefore would have little reaction toward one another.

Declaration under 37 CFR 1.132

The Declaration discloses two compositions comprising cetirizine and mannitol. One composition is a tablet formulation. One tablet comprises the two components in separate layers and the other tablet comprises the mixture in one layer. The compositions comprising the two components in the same layer experiences the formation of mannitol ester at a higher percentage, 0.61% and 2.82%, than that of the bilayer tablet, 0.21% and 0.28%. This is asserted to be unexpected. The other formulation is a dry syrup formulation. One syrup comprises the two components in separate layers and the other syrup comprises the mixture in one layer.

Examiner's Response to Arguments and Declaration

The Declaration is not persuasive. Declarant asserts that it is known in the art that polyols with low molecular weights such as mannitol react with cetirizine. Thus, the Examiner submits that it would have been obvious to place the two components in separate layers such as placing mannitol in the coating and cetirizine in the core or vice versa to inhibit them from reacting with one another. Thus, the results submitted by

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Declarant appear to be expected. Further the claims encompass a chewing gum composition, which differs from a tablet composition or a dry syrup as disclosed by the instant specification and the declaration, and therefore, even assuming, purely *arguendo*, that unexpected results have been demonstrated, the instant claims would not be commensurate in scope with the examples or the results of the instant specification.

Claim 39 is rejected.

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612